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10/529,284	08/18/2005	Jorg Mayer	ZIMR/0016	2008
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EXAMINER				
ELLIS, SUEZU Y				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/529,284

**Applicant(s)**

MAYER ET AL.

**Examiner**

Suezu Ellis

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 17-29 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-12 and 17-29 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**FINAL REJECTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-11, 17-20, 22-24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403) in view of Caruso et al. (EP 1 116 516).

With respect to claims 1, 2, 6-9, 17, 18, 19, 22, 24, 27 and 29, Parikh et al. discloses a solid dosage form for oral administration comprising a coherent matrix with a disintegration time of less than 30 seconds [0024], wherein the matrix comprises an active ingredient which is slightly soluble in a physiological fluid (poorly soluble) [0010]. Parikh et al. discloses mixing the active ingredient with matrix-forming, physiologically acceptable excipients to provide a mixture and forming the mixture into dose units (tablet) [0022] and the active ingredient is in the form of fast-releasing microcapsules (phospholipid-coated microparticles) [0012], [0025]. Parikh et al. disclose the microcapsules comprising a core (microparticle) and a shell (coating), wherein the core comprises the slightly soluble active ingredient. Since the microcapsule is considered to be rapid-releasing, the shell is also considered to have a high permeability. Parikh et al. further discloses the microcapsules having an average size of less than 10µm

[0017]. Parikh et al. fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte. Caruso et al. discloses using microparticles having shell comprising an amphiphilic (phospholipid) and alternating layers of polyelectrolytes of opposite charges, where the polymer layers are self-assembled by means of electrostatic layer-by-layer deposition [0009], [0019]. Caruso et al. further discloses controlling the permeability and porosity of the capsule by controlling the number of layers and by the selection of the polyelectrolytes used for the shell [0032], [0036]. It would have been obvious to one of ordinary skill in the art modify the composition of the shell of the microcapsule, as taught by Caruso et al., for the predictable result of controlling the release rate of the microcapsule.

With respect to claim 3, the modified Parikh et al. discloses the release of active ingredient is virtually complete within 1 minute [0025].

With respect to claim 5, the modified Parikh et al. discloses the slightly soluble active ingredient is an antihypertensive or a sedative [0013].

With respect to claim 10, the modified Parikh et al. discloses the matrix is produced by compressing a material selected from at least one of powder and granules [0022].

With respect to claim 11, the modified Parikh et al. discloses the matrix is produced by freeze-drying a substance selected from at least one of a fluid and a highly viscous composition [0011].

With respect to claim 20, the modified Parikh et al. discloses mixing the mixture with a liquid carrier (aqueous medium) to provide a solution, wherein forming the mixture into dose units includes dividing and freeze-drying the solution [0018]-[0020].

With respect to claim 23, the modified Parikh et al. discloses the active ingredient is a therapeutic [0017].

Claims 4, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. in view of Caruso et al. and further in view of Green et al. (US 2001/0055611).

With respect to claim 4, the modified Parikh et al. addresses all the limitations of claim 1, and further discloses the matrix can include mannitol and gelatin [0018]. The modified Parikh et al. fails to expressly disclose the content of gelatin and mannitol being in a ratio of 1:1 to 1:3. Green et al. illustrates in Example 2, a formulation comprising microcapsules (coated paracetamol) and gelatin and mannitol at a ratio close to 1:1. It would have been obvious to one of ordinary skill in the art to modify the ratio of the gelatin and mannitol in order to provide an optimum rapidly disintegrating solid oral dosage form that does not have an unacceptable taste (does not rely on the use of sweeteners and flavoring agents), as taught by Green et al. [0048]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 25, the modified Parikh et al. discloses the slightly soluble active ingredient is an antihypertensive or a sedative [0013].

With respect to claim 28, the modified Parikh et al. discloses the shell (coating) of the microcapsules comprise a lipid layer (phospholipid) [0025].

Claims 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. in view of Caruso et al. and further in view of Virgalitto et al. (US 2005/0089548).

With respect to claim 12, the modified Parikh et al. addresses all the limitations of claim 1, however fails to expressly disclose the matrix is produced by solidifying a composition which has been spread out into a film. Virgalitto discloses microcapsules containing active ingredients, such as pharmaceutical active ingredients, in an edible film (matrix) [0012], [0043]. Virgalitto further discloses the matrix is produced by solidifying a composition which has been spread out into a film [0074]. It would have been obvious to one of ordinary skill in the art to modify the method of making the matrix in order to create an alternative oral dosage form for patients that are unable or have a difficult time swallowing conventional oral dosage forms, as taught by Virgalitto [0002].

With respect to claim 21, the modified Parikh et al. addresses all the limitations of claim 18, however fails to expressly disclose mixing the mixture with a liquid carrier (inherent to aqueous solution) to provide a solution, wherein forming the mixture into dose units includes spreading the solution into a film and drying the film. Virgalitto

discloses the edible film is formed by mixing the mixture (microcapsules and excipients) with a liquid carrier to provide a solution, spreading the solution into a film and drying the film [0074], [0076]. It would have been obvious to one of ordinary skill in the art to modify the method of making the oral dosage form in order to create an alternative oral dosage form for patients that are unable or have a difficult time swallowing conventional oral dosage forms, as taught by Vigalitto [0002].

### ***Response to Arguments***

Applicant's arguments filed April 21, 2008 regarding the rejection under Khankari et al. (US 6,024,981) in view of Caruso et al. (WO 00/72181) have been fully considered and are persuasive, and the rejection has been withdrawn.

Applicant's arguments filed April 21, 2008, regarding the rejection under Parikh et al. (US 2002/0106403) in view of Caruso et al. (EP 1 116 516) have been fully considered but they are not persuasive.

With respect to claims 1, 18 and 24, applicant argues that Parikh or Caruso et al. would enable controlling the release rate to meet the "fast-release capsules" limitation of the claimed dosage and methods. Examiner respectfully disagrees. Parikh et al. teaches rapid-releasing microcapsules comprising a core (microparticle) and a shell (coating), wherein the core comprises the slightly soluble active ingredient. Examiner notes that the shell is also considered to have a high permeability since it allows the active ingredient to be released rapidly. Caruso et al. demonstrates an example of microcrystals (core) encapsulated with polyelectrolyte multilayers producing a rapid

release characteristics, and increasing the number of layers decreases porosity (permeability) thereby decreasing the release rate [0013], [0053]. Further, Caruso et al. teaches the polyelectrolytes and its counterions being the same materials as that of the applicant, therefore are considered to have similar properties (high permeability and fast release) [0022], [0023]. Therefore, it would have been obvious to one of ordinary skill to combine the teachings of Parikh et al. and Caruso et al. in order to create a microcapsule with the desired release rate for the predictable result of forming a rapid releasing microcapsule. Thus, applicant's arguments are not persuasive and the rejection above is maintained.

With respect to the remainder of the claims, applicant argues the deficiencies of the independent claims and fail to provide specific arguments regarding the dependent claims. Therefore, the rejection above is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone/Fax Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/  
Primary Examiner, Art Unit 1615